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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,211

04/04/2005

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,211	<b>Applicant(s)</b> KELLER, ARNOLD	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/4/2009 has been entered.

### ***Response to Arguments***

2. Examiner acknowledges Applicant's amendments including (1) cement-less implantation, (2) distal portion for insertion into the diaphyseal region of the femur and (3) the distal part comprising diaphyseal anchoring projections.

3. Applicant's arguments filed 11/4/2009, with respect to the rejection(s) of claim(s) 1-2, 4-5, 8 under Niederer (4,359,785) have been fully considered and are persuasive, because Niederer discloses cemented insertion of the prosthetic stem. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under Niederer (4,359,785) in view of Tanamal (5,755,811) and Itoman (6,190,417).

4. Examiner disagrees with Applicant's characterization of Tanamal as disclosing cemented stem insertion. Tanamal discloses cement-less implantation (col. 3 lines 51-57). In fact, Tanamal teaches the use of the fins to "cut into the bone and become embedded into the cancellous bone" (col. 3 lines 57-65).

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5. The new rejection presented below addresses Applicants amendments. First, the cement-less implantation is taught in Tanamal. This is not considered incompatible with the teaching of Niederer because they are equivalent implantation means for a given prosthetic. Secondly, both Niederer and Tanamal disclose stems that extend in the diaphyseal region. Finally, the addition of projections on the distal part of the diaphyseal stem is taught in Itoman (see 10, figs. 2 and 6, and related description).

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederer (U.S. Pat. No.: 4,359,785) in view of Tanamal et al (U.S. Pat. No.: 5,755,811) and Itoman (6,190,417).

2. Niederer discloses a hip prosthesis comprising a shaft and a femoral neck, the shaft having a proximal part comprising projecting fins **12** on the front and rear faces of the proximal part (see figs. 1-3). Each fin **12** extends from a distal end of the proximal part to a proximal end of the proximal part (see fig. 2) and has a steep medial flank (see fig. 3), each fin having a surface portion delimited by a medial edge and a lateral edge, the medial edge forming a borderline between the surface portion and the steep flank. The width of the fin increases from the distal end to the proximal end of the proximal

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part (see fig. 1), and the height of the fins decreases in a lateral direction from an edge delimiting the steep flank (see fig. 3). The prosthesis comprises a device **2** for anchoring the endoprosthesis to a diaphysis. However, Niederer fails to show the angle of the angled fin. However, it would have been an obvious matter of design choices to have a fin angle of 5 to 15 degrees, since such a modification (if any) would have involved a mere change in size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Examiner considers this feature to be an obvious design choice that would be considered when designing for ease of insertion into a prepared bone, amount of material used, bone purchase at the implantation site, etc. The level of ordinary skill in the art of hip prosthesis design and use is high, and thus the specific angle of the angled fin of Niederer would have been readily apparent and obvious in view of numerous design considerations for hip prosthesis.

3. Niederer lacks cement-less implantation. Tanamal discloses cement-less implantation (col. 3 lines 51-57) and teaches the use of the fins to "cut into the bone and become embedded into the cancellous bone" (col. 3 lines 57-65). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the prosthetic with a cement-less implantation as taught by Tanamal for the purpose of providing a direct press fit with native cancellous bone.

4. Niederer and Tanamal lack a distal portion with diaphyseal anchoring projections. Itoman teaches projections 10 on the distal portion 12 of the stem for the purpose of increasing the fixing force to the native bone and promoting the anchoring effect of the

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distal stem during healing (col. 4 lines 40-51). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the distal stem of Niederer in view of Tanamal to include projections as taught by Itoman, for the purpose of creating a stronger anchor into the native bone.

5. With respect to claims 4 and 8, Niederer fails to specify whether the height of the lateral edge of the fin is not greater than half the height of the medial edge (See fig. 3). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a lateral edge fin height that is not greater than half the height of the medial edge, since it has been held that where the general conditions of a claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

6. With respect to claims 3 and 6-7, Niederer fails to show the height of the fin above the surface of the shaft increasing from the distal end to the proximal end of the proximal part. Tanamal teaches the use of tapered fins (see fig. 3) resulting in a prosthetic with improved rotational stability (col. 3 lines 32-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the finned prosthesis as disclosed by Niederer with a taper towards the distal end of the prosthesis as taught by Tanamal for the purpose of facilitating easier insertion of the finned prosthesis.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner, Art Unit 3774

/S. G./  
Examiner, Art Unit 3774